K133155

SECTION 5 - 510(k) SUMMARY UGFT3

Medisim
Non Invasive Thermometry

Date prepared: 20th of April, 2013

1. Submitter information:

Medisim Ltd.

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Submission: 7.4.2013

AUG 2 8 2013

2. Device information:

Trade Name: Up-Grade Forehead/ Underarm/Behind Ear Thermometer, UGFT3, FHT7**

Common name: Electronic Clinical Thermometer

Product code: FLL; Product class: II

Product classification: Clinical electronic thermometer, § 880.2910

Product Panel: 80 General hospital

3. Substantial equivalent:

a. Medisim's Dual Mode Up Grade Forehead/Underarm Thermometer, cleared under K051422

b. Vicks (KAZ) Behind Ear Thermometer, cleared under K103839

c. NIR Thermometer, cleared under K090386

4. Description of the new device:

The UGFT3 is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead and/or underarm and/or behind the ear as measurement sites. The UGFT3 is utilizing the Rapid Accurate Temperature Establishment (R.A.T.E.™) technology, a technology based on the heat conduction principle, for determination of body temperature. Utilizing the R.A.T.E.™ technology, the device rapidly samples the heat flowing from the blood vessels to the skin surface. Then, based on the heat flow, the device calculates the blood vessel temperature, and then corrects this value to the body core temperature.

User operation of the UGFT3 is identical to the operation of the Dual Mode Up Grade Forehead/Underarm Thermometer, cleared under K051422. The device allows user control by use of buttons located on the front panel of the device and the measured body temperature is displayed on an LCD screen, in C° or F° units. The UGFT3 has an identical hardware as the UGFT2, as it uses the same thermistor sensor and electronic processing unit, however, the UGFT3 has a modified proprietary software algorithms.

Device is made of ABS plastic and silicone rubber

5. Intended use of the device

The device indication for use is:

The UGFT3 is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the temple (forehead) and/or underarm (axilla) and/or behind the ear as measurement sites.

The UGFT3 is substantially equivalent regarding the intended use to the Dual Mode Up Grade Forehead/Underarm Thermometer cleared under K051422 and the Vicks Behind Ear

Thermometer cleared under K103839. The UGFT3 and it's predicate devices are intended for use for determination of core -body temperature through measurements taken on the skin above a blood vessel.

The Dual Mode Up Grade Forehead/Underarm Thermometer is intended to measure using the forehead and underarm sites only; the Vicks Behind Ear Thermometer is intended to measure using the behind the ear site only; the new UGFT3 is intended to measure either in the underarm, and/or behind the ear and/or the forehead.

The UGFT3 is substantially equivalent to NIR Thermometer regarding the presence and function of MTR Feature (Medication Timer Reminder).

6. Comparison to the predicate devices:

Intended Use and Technological Characteristics	**UGFT3**	**Dual Mode Up Grade Forehead/Underarm Thermometer cleared under K051422**	**Vicks Behind Ear Gentle Touch Thermometer cleared under K103839**	**NIR Thermometer K090386**
Product Code / Class	FLL / II	FLL / II	FLL / II	FLL / II
Indications	A non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead and/or axilla and/or behind the ear sites as measurement sites.	A non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead and/or axilla as measurement sites.	A non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using behind the ear as measurement site.	The NIR is non sterile non-invasive infrared thermometer intended for the intermittent calculation of human body temperature of people of all ages for home and professional use.
Population	All age groups	All age groups	All age groups	All age groups
Operational Modes (Measurement Sites)	Forehead Axilla Behind the ear- above the PAA (posterior auricular artery).	Forehead Axilla	Behind the ear	Forehead
Thermometer Type	Clinical Electronic	Clinical Electronic	Clinical Electronic	Clinical Electronic

Intended Use and Technological Characteristics	**UGFT3**	**Dual Mode Up Grade Forehead/Underarm Thermometer cleared under K051422**	**Vicks Behind Ear Gentle Touch Thermometer cleared under K103839**	**NIR Thermometer K090386**
	Thermometer	Thermometer	Thermometer	Thermometer
Principle of Operation	Predictive Thermometer	Predictive Thermometer	Predictive Thermometer	Infra Red Thermometer
Labeling	Instructions For Use	Instructions For Use	Instructions For Use	Instructions For Use
Major Components	Main (Control & Processing) Unit including display, and Probe Tip	Main (Control & Processing) Unit, including display, and Probe Tip	Main (Control & Processing) Unit, including display, and Probe Tip	Main (Control & Processing) Unit including display, and Probe housing
Sensor	Thermistor	Thermistor	Thermistor	Thermopile
Display	LCD (20 mm x 19.6 mm)	LCD (20 mm x 19.6 mm)	LCD (20.4mm x 20.4 mm)	LCD (20 mm x 19.6 mm)
Power Requirements	2 x 1.5V AAA Batteries	2 x 1.5V AAA Batteries	1 x CR2032 (3V lithium battery)	3x1.5V AAA Batteries
Patient Contact Materials	Case – ABS Plastic Probe Tip – Stainless Steel , ABS plastic and silicon rubber	Case – ABS Plastic Probe Tip – Stainless Steel , ABS plastic and silicon rubber	Case – ABS Plastic, rubber	ABS plastics
Clinical Measurement Display	Temperature	Temperature	Temperature	Temperature
Units of Measurement	°C, °F	°C, °F	°C, °F	°C, °F
Clinical Measurement Range	35.0°C to 42.0°C 95.5°F to 107.6°F	35.0°C to 42.0°C 95.5°F to 107.6°F	35.5°C to 42.0°C 95.9°F to 107.6°F	22.0°C to 40.0 °C (71.6°F to 104.0°F)
Ambient Temperature for measurement	16°C to 40°C 60.8°F to 104.0°F	16°C to 40°C 60.8°F to 104.0°F	10°C to 40°C 50°F to 104.0°F	16.0 °C to 40.0°C (60.8 °F to 104 °F)
Environment	15% to 95% RH non-	15% to 95% RH non-	15% to 95% RH	15% to 95% RH

Intended Use and Technological Characteristics	**UGFT3**	**Dual Mode Up Grade Forehead/Underarm Thermometer cleared under K051422**	**Vicks Behind Ear Gentle Touch Thermometer cleared under K103839**	**NIR Thermometer K090386**
	condensing	condensing	non-condensing	non-condensing
Medication Timer Reminder with alert (MTR)	Timer to alert the patient when to take next dosage	None	None	Timer to alert the patient when to take next dosage
Technical Accuracy	ASTM E1112-00	ASTM E1112-00	ASTM E1112-00 ASTM E1965-98	ASTM E1112-00 ASTM E1965-98
Response Time	6-8 seconds	6-8 seconds	1 second	2 seconds
Activation	Automatic body detection	Automatic body detection	Manually	Automatic body detection
Dimensions	Length: 10.0cm (3.9") Width: 5.2cm (2.05") Depth: 3.2cm (1.25")	Length: 10.0cm (3.9") Width: 5.2cm (2.05") Depth: 3.2cm (1.25")	Length: 14.4cm (6") Width: 4.2cm (1.65") Depth: 2.4cm (0.95")	Length: 10.5cm (4.1") Width: 4.5 cm (1.77") Depth: 3.5 cm (1.37")
Weight (including batteries)	44gr	44gr	76gr	70gr

The differences and similarity between UGTF3 Device and its predicates:

UGTF3 Vs Dual Mode Up Grade Forehead/Underarm:

The devices are similar in:

- Similar principal of operation and user interface
- Measuring sites: Forehead/Under arm

Devices are different:

- Additional measurement location for UGFT3: Behind-ear;

UGTF3 Vs Vicks Gentle Touch device:

Devices are similar in:

- Measuring location: Behind Ear

Devices are different in:

- Technological principal of operation
- Additional measuring site of the UGFT3: Forehead /under arm

UGTF3 Vs NIR Thermometer:

Devices are similar in:

- MTR- Medication Reminder Timer feature
- Measuring location Forehead

Devices are different in:

- Technological principal of operation
- Additional measuring site of the UGFT3: Forehead /under arm

Essentially, the intended use between the two predicate thermometers, Upgrade dual mode and Vicks gentle touch, are due to the fact that the new UGFT3 device is the only device that is capable of measuring temperature in all three locations.

Comment: The predicate NIR thermometer is presented in this application to demonstrate similarity to the new UGFT3 device MTR (Medication Reminder Timer) feature only, The other characteristics of the NIR thermometer are is irrelevant to the comparison to the UGTF3 and it.

7. Device Testing (Software Validation, Bench and Clinical test)

The new device UGFT3 was tested in order to fully validate its performance under the following tests:

A. Software Validation Tests.

B. Performance testing:

1. Bench testing according to ASTM E-1112-00

2. Clinical testing behind the ear temperature measurement accuracy validation through a clinical study according to ISO80601-2-56.

A. Software Validation:

The software was validated to assure the full functionality of the device UGFT3.

The software validation protocol and relevant ECO report can be found in section 14 of this submission. The software validation information includes the following:

- Hardware architecture diagram of up-grade forehead thermometer
- General software flowchart of up-grade forehead thermometer

- Summary of system requirement specification (SRS)
- Summary of system test plan (STP)
- Device Hazard Analysis

The device software was validated successfully and changes in software are implemented successfully as device is fully functional.

B. 1. Behind the ear temperature measurement accuracy validation through Performance of a clinical study:
The primary objective of the study was to demonstrate the effectiveness of the new device UGFT3 (also referred to in the clinical study report as FHT7) for measurements behind the ear. Clinical accuracy of the UGFT3 was evaluated by comparing to temperature measurements taken using the Vicks behind ear Thermometer to validate the compliance of the behind the ear site. The secondary objective was to test.the similarity between temperature measured on the forehead site (above the STA) compared to the temperature measured on the behind the ear site (above the PAA) using the UGFT3.
Total subjects were 239, Subjects were 138 males and 101 females, within ages range of 0-91 years (The full clinical study report is detailed in section 17).
Subjects with and without fever were included in the clinical study, Subjects from all groups were covered.
The UGFT-3 was used safely without causing any discomfort to the patients. There were no observations or reports of adverse effects. The UGFT-3 was found to be as reliable as Vicks Behind the Ear thermometer, cleared under K103839.

B. 2. Bench testing Bench testing was performed in accordance to ASTM E-1112-00
The following tests were performed on the UGTF3 device:
- o Display Temperature Range Test
- o Lab Accuracy Test
- o Operating Environment Test
- o Storage Environment Test
- o Drop Test

The device passed all bench tests successfully as it withstands acceptance criteria for each and every bench test performed.

8. Conclusions

The clinical and non-clinical testing, as well as the clinical research and previous testing done on the original device prove that the UGFT3 device is safe and effective as the cleared predicate devices.

The UGFT3 thermometer (K131155) is substantially equivalent to the UGFT2 thermometer , cleared under K051422, in the principal of operations and the measuring sites of forehead and underarm; the UGFT3 was found substantially equivalent to the Vicks thermometer, cleared under K103839 ,in regards of the measuring site - behind ear; and The UGFT3 thermometer is substantially equivalent to the NIR thermometer, cleared under K090386, in regards to the Medication Timer Reminder feature.

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the UGFT3 Thermometer is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

**Notes:

1. Throughout the submission the device is referred to as UGFT3 or FHT7 which is another trade name for the device, used in the device's labeling.

2. The dual mode upgrade forehead thermometer is referred to as UGFT2/FHT2/FHT5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Medisim, Limited
Mr. Moshe Yarden
Quality Assurance Manager
G.G Communications Center
Neve Ilan
JERUSALEM IL 90850

Re: K131155
Trade/Device Name: Up-grade forehead/underarm/behind ear thermometer (UGFT3)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 11, 2013
Received: July 18, 2013

Dear Mr. Yarden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K131155

Device Name: Up-grade forehead/underarm/behind ear thermometer (UGFT3)

Indications For Use:

The UGFT3 is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the temple (forehead); and/or underarm (axilla); and/or behind the ear as measurement sites.

Prescription Use _____ AND/OR Over-The-Counter Use ___√____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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